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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,980	07/31/2003	Christopher J. Calhoun	MA9604P	2197

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EXAMINER

BETTON, TIMOTHY E

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/631,980	Applicant(s) CALHOUN ET AL.	
	Examiner TIMOTHY E. BETTON	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 and 53-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 and 53-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1 page, 3/21/2008; 2 pages, 18 June 2009.

DETAILED ACTION

Applicants' Remarks filed on 17 February 2009 have been acknowledged and duly made of record.

Previous Obviousness Double Patenting Rejection

The ODP made in last office action is improper and the Terminal Disclaimer filed on 17 February 2009 should not have entered as a TD has already been filed and put on record over USPN 6, 673,362). The ODP rejection is hereby withdrawn.

Response to Arguments

Applicants' aver the Indefiniteness Rejection because of reasoning drawn to an explanation found in the specification to support this limitation in the claim. Upon further reconsideration, Examiner hereby withdraws the previous claim Rejection 35 USC § 112, 2nd paragraph .

Applicants' aver the Double-Patenting Rejection because of the submission of a Terminal Disclaimer filed on 16 April 2007 which claims to address and overcome the said Double-Patenting Rejection.

Applicants' aver the Prior-Art Rejection because:

(1) Totakura et al. fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), non-porosity (claim 1), and a thickness of about .001 mm to 0.300 mm (claims 1 and 25);

(2) Vyarkaram et al. fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), and non-porosity (claim 1);

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(3) *Tang et al.* fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), and non-porosity (claim 1);

(4) *Lemperle et al. (059)* fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), non-porosity (claim 1), and a thickness of about .001 mm to 0.300 mm (claims 1 and 25);

(5) *Lemperle et al. (473)* fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), and non-porosity (claim 1); and

(6) *Mansmann.* fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), non-porosity (claim 1); and a thickness of about .001 mm to 0.300 mm (claims 1 and 25).

Applicants' arguments are considered but are not found persuasive because of the limitation disclosed in claim drawn to *comprising*.

Comprising language of the current invention is broad and is not exclusive in view of applicants' recent submission of Remarks. Thus, the methods and teachings of references 1-6 *supra* are reasonably maintained.

Further, In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the methods and teachings of the all the references *supra* obviate the claimed invention. The principal reference Totakura et al. teaches the optimization characterization of the construction and configuration of transdermal patches. The specific limitations of the current claims are functional to the common characteristic(s) of a typical resorbable adhesion-inhibition membrane. Additionally, the language of the instant claims are redundant in the way of further limiting the characteristics of the said membrane.

Further still, the instant specification is absent as to how these limitations attributed to the membrane are in any way distinguished and/or distinct in view of the current claim limitations.

For the reasons already made of record, the Prior-Art rejection is maintained.

Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1-32 and 53-55 are pending for further prosecution on the merits.

Claim Rejection- 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-32 and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totakura et al. (USPN 5,795,584) , Vyarkarnam et al (USPN 6,333,029) and Browall et al. (USPN 3,874,986) in view of Baars et al. (USPN 6,132,668) and Tang et al. (USPN 5,412,068).

Totakura et al. teach surgical adhesion barriers and methods of using such surgical adhesion barriers. Surgical adhesion barriers according to the present invention have at least one layer of a bioabsorbable material comprising copolymers and/or block copolymers derived from trimethylene carbonate. Alternatively, a multilayer surgical structure having one or more bioabsorbable layers superimposed on a non-absorbable layer is useful for minimizing or preventing formation of fibrous adhesions between a healing trauma site and adjacent surrounding tissue. Alternatively, a bioabsorbable non-woven fabric in adherent contact with at least one bioabsorbable layer of foam, film, mesh, web or woven fabric is also provided. One or more medicinal agents may be interposed between or disposed within any of the aforementioned layers (abstract only).

Totokura et al. teach non-porous non-absorbable layered membrane. The disclosure of non-permeability is an essential element, which is also central to claimed invention. Totokura et

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al. teach lactide and epsilon caprolactone. Further, Totokura et al. teach a viscosity property of 0.9: A 20/80 mole percent glycolide/trimethylene carbonate copolymer was prepared in a reactor by combining previously dried 53.13 grams of glycolide and 186.87 grams of trimethylene carbonate and polymerizing at 160.degree. C. for 24 hours in the presence of 0.05 grams of stannous octoate. The polymer was extruded from the reactor and post treated to remove any residual monomer present in the polymer. **The inherent viscosity of the polymer was 0.9** (column 11, line 44-51).

The instant invention discloses a viscosity property of about 1 g/dL. In Example 4 (column 12, lines 44-51), the inherent viscosity of this polymer is 0.6 to 1.1 dl/g. Additionally, the Examples teach thickness ranges of membranes from 1 cm X 2 to 2 cm X 3 cm (columns 11-18).

These ranges of Totokura et al. do not specifically read on the particular ranges as disclosed within the instant specification but do encompass the ranges as disclosed. Applicants' specifically disclose:

Furthermore, the Examiner further alleges in the same paragraph : the Office Action that Totokura et al. discloses ranges that "encompass the ranges disclosed in ['sic] subject invention." Applicants find no logic or basis for this statement. In any event, to the extent that Totokura et al. teaches thickness ranges of membranes from 1 cm x 2 to 2 cm x 3 cm, as alleged by the Examiner, Applicants respectfully submit that these ranges are not encompassed by the presently claimed invention. In particular, the range of "0.001 mm to about 0.300 mm" in Applicants' independent claim 1 converts to a range of 0.0001 cm to 0.3 cm, and the range of "about 0.010 mm to about 0.030 mm" in Applicants' independent claim 25 converts to a range of 0.001 cm to about 0.003 cm. Neither of these claimed ranges are encompassed by the Totokura et al. numbers of 1 cm x 2 to 2 cm x 3 cm.

Totokura et al. is silent with regard to the thickness of membrane layers in terms of differences in mm.

Vyarkarnam et al. teach three-dimensional inter-connected open cell porous foams that have a gradient in composition and/or microstructure through one or more direction. These foams can be made from a blend of absorbable and biocompatible polymers that are formed into foams having a compositional gradient transitioning from predominately one polymeric material to predominately a second polymeric material. These gradient foams are particularly well suited to tissue engineering applications and can be designed to mimic tissue transition or interface zones (Abstract).

Vyarkarnam et al. teach a poly-L-lactide, poly-DL-lactide (column 1, lines 39 and 40). Vyarkarnam et al. teach a mole ratio of epsilon caprolactone to p-dioxanone of from about from 30:70 to about 70:30) elastomeric copolymers of p-dioxanone and trimethylene carbonate (preferably having a mole ratio of p-dioxanone to trimethylene carbonate of from about 30:70 to about 70:30), elastomeric copolymers of trimethylene carbonate and glycolide (preferably having a mole ratio of trimethylene carbonate to glycolide of from about 30:70 to about 70:30), elastomeric copolymer of trimethylene carbonate and lactide including L-lactide, D-lactide, blends thereof or lactic acid copolymers (preferably having a mole ratio of trimethylene carbonate to lactide of from about 30:70 to about 70:30) and blends thereof (column 10, lines 60-67). Instant invention is drawn toward a 70:30 poly (L-lactide-co-D, L,-lactide) (pg 5).

Vyarkarnam et al. do not teach non-porous membranes.

However, Browall et al. does teach the ultrathin non-porous membranes for use in the practice of this invention are prepared by the Ward process by casting on a confined liquid surface. A pair of movable longitudinally-extending barriers initially spaced apart a small

distance and in contact with the liquid surface are employed, first, to accommodate the casting solution there between and second by relative separation thereof to controllably permit spreading of the casting solution over the surface of the film-support liquid. Water is the preferred film support liquid (abstract only).

Totakura et al., Vyarkarnam et al. and Browall et al. do not specifically teach the limitations drawn to a bias toward one to two axes.

However, Baars et al. does teach the formation of thick films having a biaxial molecular orientation. Such films are prepared in accordance with the present invention from rod-like extended chain aromatic-heterocyclic ordered polymers. Such films have high tensile strength, modulus, and environmental resistance characteristics. A preferred ordered polymer for use in the present invention is poly (para-phenylenebenzo bithiazole), (PBT), a compound having the structure [as disclosed]. The present invention is also directed to methods and apparatus suitable for producing biaxially oriented films, coatings, and like materials from ordered polymers, preferably PBT (abstract only).

Baars et al. further discloses the inventive objective and reasoning drawn to the preparation and process of manufacturing such polymers. The scientific engineering and manipulation of such polymers with variable sizes, widths, thicknesses, elongation requirements, smoothness, rigidity, etc. is well-suggested and supported in the present Baars et al. reference.

Accordingly, Tang et al. teach medical devices formed totally or in part from homopolymers or copolymers comprising recurring carbonate moieties (Abstract).

Tang et al. teach bioresorbable polymers, which are used in the fabrication of devices for implantation in living tissue for several decades. Medical application of such polymers includes absorbable sutures, haemostatic aids and, recently, intraosseous implants and control-release drug delivery systems.

Claims 6-10, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totakura et al., Vyarkarnam et al., Browall et al., Baars et al. and Tang et al. as applied to claims 1-5, 11, 12, 15-17, 18, 19-32 and 53-55 above, and further in view of Lemperle et al. (USPN 6391059), Lemperle et al. (USPN 6280473), and Mansmann, K. (USPN 6530956).

Lemperle et al. (059) teach a resorbing flexible implant in the form of a continuous macro-porous sheet (42) is disclosed. The implant is adapted to protect biological tissue defects, especially bone defects in the mammalian skeletal system, from the interposition of adjacent soft tissues during in vitro repair. The membrane (42) has pores with diameters from 20 microns to 3000 microns. This porosity is such that vasculature, and connective tissue cells derived from the adjacent soft tissues including the periosteum, can proliferate through the membrane into the bone defect. The thickness of the sheet is such that the sheet has both sufficient flexibility to allow the sheet to be shaped to conform to the configuration of a skeletal region to be repaired, and sufficient tensile strength to allow the sheet to be so shaped without damage to the sheet. The sheet provides enough inherent mechanical strength to withstand pressure from adjacent musculature, and does not collapse (Abstract).

Lemperle et al. (059) teach a membrane capable of resorbing into the mammalian body within a period of 24 months from the initial implantation (column 6, lines 64-67), which is obvious over instant claim 1.

Lemperle et al. (059) teaches molecular orientation in regard to a single axis or axes (at least two), which is obvious over instant claim 7 of subject invention (column 14, line 1; line 43). Further, Lemperle et al. teach specific additives (column 5, lines 66-67), which is obvious over instant claim 13 of subject invention.

Lemperle et al. (059) does not teach the membrane thickness of about 0.001 mm to about 0.300 mm. Lemperle et al (059) does not teach sealed sterile packaging.

However, Lemperle et al (473) does teach membrane thickness ranges which fall within the instant ranges of 1 micron to 300 microns (column 3, line 62; column 6, lines 9 and 57-60), which is obvious over instant claim 1. Lemperle et al. (473) also teach a range which encompasses instant inventions highest range (column 16, line 9).

Additionally, Mansmann, K (USPN 6530956) does teach a resorbable scaffold contained in a sealed sterile package used to help transplanted chondrocytes or other cells generate new cartilage in a damaged joint (column 9, line 15), which is obvious over instant claim 14.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to recognize with a reasonable expectation of success via the combining and/or incorporating together the methods, compounds, and teachings of Totokura et al., Vyarkarnam et al., Browall et al., Baars et al and Tang et al. incorporated with the teachings of Lemperle et al. and Mansmann, K. The references *supra* in combination with interchangeable modifications embody and encompass the central elements of claimed invention as explained above. The motivation to combine is present in Totokura et al. which encompasses elements of Vyarkarnam et al. Vyarkarnam et al., in addition, teach elements that are not readily disclosed within Totokura, but encompass further elements obvious over the instant claims and the subject

invention. Browall et al. and Baars et al. cure the deficiencies of the other references as disclosed via explanations replete with embodiments which describe plethora of properties of an amorphous polylactide and/or non-porous membranes and derivatives thereof. In addition, Browall et al. and Baars et al. provide the most comprehensive motivation to combine all the references via insight into the actual scientific engineering which is readily reproducible and is well-established in the art of polymer manipulation. Lemperle et al. and Mansmann et al. are the motivation to further combine by encompassing the specific claim limitations of instant claims 6-14.

Principally, the content and scope that both the prior art and instant invention share in common, is drawn to a membrane possessing variable and highly modifiable design characteristics. Obviousness, on the face lies with overlap of the same general functions of a membrane.

The differences between the current invention and the prior art, respectively, is that the current invention is an admitted modification of functional construction which claims improvement based on alleged distinctness whereas the prior art teaches embodiments which vary in functional construction. However, applicants' invention is not adequately established based on silence in the specification disclosing any mention on the term "adhesion-inhibition". The references as cited above adequately encompass and teach aspects of claimed invention.

Further, based upon the limitation in the claims drawn to inhibiting adhesions and scarring, the references *supra* adequately address the scarring limitation by virtue of inhibiting adhesions, reducing inflammation, and the moderation of healing trauma associated with adhesion and inflammation which leads to scarring. It would be readily apparent to the one of

skill that the methods and teachings of the references *supra* would either directly or indirectly affect the healing process in order to reasonably reduce the conditions that contribute to scarring.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY E. BETTON whose telephone number is (571)272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/
Primary Examiner, Art Unit 1617

TEB